

**REMARKS**

The Examiner is thanked for the due consideration given the application.

Upon entry of this amendment, claims 8 and 19-36 are pending in the application. Claim 7 is canceled by this amendment. Claim 8 has been amended to stand as an independent claim by generally incorporating subject matter from canceled claim 7. Claim 19 has been amended to remove recitations that provoked a rejection. Claims 24-26 and 32-34 have been amended to better reflect the disclosure at page 7 of the specification and to better set forth the invention being claimed.

Acknowledgement of the allowability of claims 22 and 30 is noted with appreciation.

No new matter is believed to be added to the application by this amendment.

Entry of this amendment under 37 CFR §1.116 is respectfully requested because it cancels a claim and presents claim amendments that instantly overcome rejections, thereby reducing issues for appeal.

**Rejections Under 35 USC §112, First Paragraph**

Claims 7, 8 and 19 have been rejected under 35 USC §112, first paragraph, as not being enabled. Claims 24-26 and 32-34 have been rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. These rejections are respectfully traversed.

The Official Action asserts that there is insufficient enablement for the limitation (in claims 7 and 19) "wherein the method comprises a maximum of 4 precipitation steps, and the method omits employment of phenol, high-speed centrifugation, ultracentrifugation and chromatography." However, this limitation has been removed from the claims by this amendment, rendering this rejection moot.

The Official Action asserts that there is insufficient written description for the units set forth in claims 24-26 and 32-34. However, claims 24-26 and 32-34 have been amended to better reflect the disclosure at page 7 of the specification.

The instant claims are thus in full compliance with 35 USC §112, first paragraph. This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

#### **Art Rejections**

Claims 7, 8, 19, 23 and 31 have been rejected under 35 USC §102(b) as being anticipated by ELLWOOD et al. (U.S. Patent 5,563,051). Claims 7, 8, 19, 21-23, 27-29, 35 and 36 have been rejected under 35 USC §103(a) as being unpatentable over ELLWOOD et al. in view of HASLER et al. (U.S. Patent 6,891,037) and LANDER et al. (U.S. Patent 6,410,025). These rejections are respectfully traversed.

The present invention pertains to a method of recovering a polysaccharide from a fermentation broth that

includes the utilization of anionic and/or cationic detergents. Alcohol is used to precipitate fractions.

ELLWOOD et al. pertain to the production of hyaluronic acid by the fermentation of *Streptococcus*. ELLWOOD et al. fail to anticipate the present invention at least by the following aspects:

*Anionic surfactant*

- ELLWOOD et al. do not use alcohol in combination with the anionic surfactant, whereas the present invention does.

- ELLWOOD et al. use an anionic surfactant to lyse the cell and therefore extract the cell and therefore extract the polysaccharide from the biomass, whereas in the present invention, an anionic surfactant is used to precipitate impurities.

*Cationic surfactant*

- ELLWOOD et al. use a cationic detergent to get rid of nucleic acids by precipitating them, whereas the invention uses cationic detergent to precipitate the polysaccharide.

The claims of the present invention are therefore clearly not anticipated by ELLWOOD et al.

Regarding unpatentability, there are differences between claims of the present invention and ELLWOOD et al. in the way that the anionic and cationic surfactants are used in the purification process of the present invention. The Official Action acknowledges that ELLWOOD et al. fail to teach a sodium

deoxycholate anionic detergent, a hexadecyltrimethyl ammonium bromide cationic surfactant and that the polysaccharide is obtained from *Haemophilus influenza* type b.

HASLER et al. and LANDER et al. both pertain to a purification process with a single step, as summarized below. Both HASLER et al. (Example 1) and LANDER et al. (Examples 1 and 2) start from a polysaccharide powder(s) or solution that have been (partially) purified using a classical purification process. They carry out one single purification step on the dissolved powder(s) or the solution, in a suitable aqueous solvent. Both documents do not teach or infer to modify the "classical purification process" that was first carried out.

One of skill and creativity in the art would fail to combine ELLWOOD et al. with LANDER et al. for at least the following reasons.

LANDER et al. use as the **sole** purification step a precipitation of the polysaccharide using a cationic detergent. The precipitated polysaccharide is subsequently dried and dissolved into an **organic** solvent to be chemically derivatized and conjugated. ELLWOOD et al. use a cationic detergent in a **multistep process and for a distinct goal** different from that of LANDER et al. (see above, and in LANDER et al. Background of the Invention ". . . accommodate the transition from an aqueous to an organic solvent. . ."). There is no teaching or inference in ELLWOOD et al. to use a cationic detergent in another way, let

alone to use a cationic detergent the way LANDER et al. did. Furthermore, there is no teaching or inference in LANDER et al. to modify its single step process into a multistep process. Therefore, one of ordinary skill and creativity would not combine ELLWOOD et al. and LANDER et al.

Even if the skilled and creative person would hypothetically combine ELLWOOD et al. and LANDER et al., this person would still not arrive at the present invention, since none of these references disclose or infer the use of an anionic detergent in the presence of alcohol.

Furthermore, the skilled and creative person would never combine ELLWOOD et al. with HASLER et al. for at least the following reasons.

HASLER et al. use as the **sole** purification step an anionic detergent in combination with alcohol to precipitate the endotoxins present in a polysaccharide fraction. ELLWOOD et al. use an anionic detergent in a multistep process and for a goal fundamentally different from that of HASLER et al. (see above). There is no teaching or inference in ELLWOOD et al. to use an anionic detergent in another way, let alone to use an anionic detergent the way HASLER et al. did. Furthermore, there is no teaching or inference in HASLER et al. to modify its single step process into a multistep process. Therefore, the skilled person would not combine ELLWOOD et al. with HASLER et al.

Also, even if one of skill and creativity in the art could combine ELLWOOD et al. with LANDER et al. and HASLER et al., there is no indication of what the resulting process would look like. A one-step process? A multistep process? To infer such a process would only be achievable by hindsight reconstruction.

In contrast, the present invention is a combination of steps combining several features. In contrast:

- ELLWOOD et al. pertain to a multistep purification process, where an anionic and a cationic detergent are used in a distinct way that is different from that of the present invention.

- HASLER et al. pertain to using anionic detergent in the presence of alcohol as a sole purification step.

- LANDER et al. pertain to the sole of a cationic detergent to precipitate the polysaccharide as a sole purification step.

However, the combination of steps in the claims of the present invention is neither disclosed nor inferred in the applied art references.

One of ordinary skill and creativity would thus fail to produce independent claims 8 and 19 of the present invention from a knowledge of ELLWOOD et al., HASLER et al. and LANDER et al. A *prima facie* case of unpatentability has thus not been made.

Claims depending upon claims 8 or 19 are believed to be patentable for at least the above reasons.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

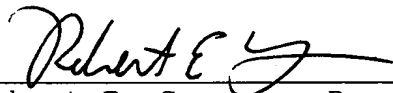
**Conclusion**

It is believed that the rejections have been overcome, obviated or rendered moot and that no issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

  
\_\_\_\_\_  
Robert E. Goozner, Reg. No. 42,593  
209 Madison Avenue, Suite 500  
Telephone (703) 521-2297  
Telefax (703) 685-0573  
(703) 979-4709

REG/lk